



Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

	Complete if Known			
Application Number 10/586,107-Conf. #1782				
iling Date	July 14, 2006			
irst Named Inventor	Giampiero De Luca			
Art Unit	1614			
xaminer Name	Not Yet Assigned	_		
Attorney Docket Number	30694/39646B			

	U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	A1	US-7,144,577	12-05-2006	Torres			

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T°			
	B1	WO 00/23097	04-27-2000	Sahltech I Goeteborg AB		Г			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	C1	ARIOGLU et al., Efficacy and safety of troglitazone in the treatment of lipodystrophy syndromes, Ann. Intern. Med., 133(4):263-274, 2000.	
	C2	BARBARO et al., An open-label, prospective, observational study of the incidence of coronary artery disease in patients with HIV infection receiving highly active antiretroviral therapy, Clin. Ther., 25(9):2405-2418, 2003.	
	C3	BECKER et al., Isolation and characterization of a sulfoxide and a desamido derivative of biosynthetic human growth hormone, Biotechnol. Appl. Biochem., 10:326-337, 1988.	L
	C4	BEWLEY et al., Sequence comparison of human pituitary growth hormone, human chorionic somatomammotropin, and ovine pituitary growth and lactogenic hormones, Int. J. Peptide Protein Res., 4:281-287, 1972.	
	C5	BRINKMAN, Mitochondrial toxicity of nucleoside analogue reverse transcriptase inhibitors, Antiviral Ther., 4(Suppl 2):25 [Abstract 009], 1999.	
	C6	CARR et al., A syndrome of peripheral lipodystrophy hyperlipidaemia and insulin resistance in patients receiving HIV protease inhibitors, AIDS, 12:F51-F58, 1998.	
	C7	CARR et al., An objective lipodystrophy severity grading scale derived from the lipodystrophy case definition score, JAIDS, 33:571-576, 2003.	
	C8	CARR et al., HIV lipodystrophy: risk factors, pathogenesis, diagnosis, and management, AIDS, 17(Suppl 1):S141-S148, 2003.	
	C9	CARR et al., Lipodystrophy associated with an HIV-protease inhibitor, N. Engl. J. Med., 339:1296, 1998.	Г
	C10	CHEN et al., The human growth hormone locus: nucleotide sequence, biology, and evolution, Genomics, 4:479-497, 1989.	
	C11	DE NOTO et al., Human growth hormone DNA sequence and mRNA structure: possible alternative splicing, Nucleic Acids Res., 9(15):3719-3730, 1981.	
	C12	ENGELSON et al., Effect of recombinant human growth hormone in the treatment of visceral fat accumulation in HIV infection: interm analysis, Antiviral Ther., 4:(Suppl 2):19 [Abstract 006], 1999.	
	C13	ENGEL SON et al., Fat distribution in HIV-infected patients reporting truncal enlargement quantified by whole-body magnetic resonance imaging, Am. J. Clin. Nutr., 69:1162-1169, 1999.	
	C14	FRIIS-MOLLER et al., Combination antiretroviral therapy and the risk of myocardial infarction, N. Engl. J. Med., 349(21):1993-2003, 2003.	
	C15	Gertler et al, Inhibition of lactogenic activities of ovine prolactin and human growth hormone (hGH) by a novel form of a modified recombinant hGH, Endocrinol., 118(2):720-726, 1986.	
Examiner Signature		Date Considered	

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	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	2	of	3	Attorney Docket Number 30694/39646B		

C16	GHIGO et al., Arginine potentiates but does not restore the blunted growth hormone response to growth hormone-releasing hormone in obesity, Metab., 41:560-563, 1992.	
C17	GOEDDEL et al., Direct expression in Escherichia coli of a DNA sequence for human growth hormone, Nature, 281:544-548,	
C18	GRAFF et al., Human somatotropin: selective removal with trypsin of residues 135-145 from the hormone molecule with no loss of biological activities, J. Biol. Chem., 257(5):2365-2369, 1992.	
C19	International Search Report, PCT/EP2005/000758, European Patent Office, 28 April 2005.	
C20	KOTLER et al., Metabolic abnormalities: fat redistribution, glucose metabolism, cardiovascular disease, HIV/AIDS 1999 Annual Update, hiv.medscape.com, 1999.	
C21	KOTLER et al., Studies of body composition and fat distribution in HIV-infected and control subjects, JAIDS, 20:228-237, 1999.	
C22	KRAVCIK, HIV lipodystrophy: a review, HIV Clin. Trials, 1(3):37-50, 2000.	
C23	KRENTZ et al., Anthropometric, metabolic, and immunological effects of recombinant human growth hormone in AIDS and AIDS-related complex, JAIDS, 6:245-251, 1993.	
C24	LEWIS et al., A naturally occurring structural variant of human growth hormone, J. Biol. Chem., 253(8):2679-2687, 1978.	П
C25	LEWIS et al., Altered proteolytic cleavage of human growth hormone as a result of deamidation, J. Biol. Chem., 256(22):11645-11650, 1981.	
C26	LEWIS et al., Enhancement of the hyperglycemic activity of human growth hormone by enzymatic modification, Endocrinol., 101(5):1587-1603, 1977.	П
C27	LEWIS et al., The 20,000-dalton variant of human growth hormone: location of the amino acid deletions, Biochem. Biophys. Re.s Comm., 92(2):511-516, 1980.	╗
C28	MARTIAL et al., Human growth hormone: complementary DNA cloning and expression in bacteria, Science, 205(10):602-607, 1979.	
C29	MAUSS et al., Successful treatment of PI-induced visceral abdominal-fat accumulation with R-human growth hormone, AIDS, 12(Suppl 4):145, 1998.	
C30	MERCIE et al., Case report of lipodystrophy observations in patients naïve of protease inhibitor treatment, aquitaine cohort 1999, Antiviral Ther., 4(Suppl 2):42 [Abstract 018], 1999.	
C31	MILANO et al., Two case reports of unusual lipomatous growths associated with combination antiretroviral therapy, Antiviral Ther., 4(Suppl 2):56 [Abstract 042], 1999.	
C32	MILLER et al., Visceral abdominal-fat accumulation associated with use of indinavir, Lancet, 351:871-875, 1998.	
C33	REITMAN et al., Lipoatrophy revisited, Trends Endocrinol. Metab., 11(10):410-416, 2000.	7
C34	RIETSCHEL et al., Assessment of growth hormone dynamics in human immunodeficiency virus-related lipodystrophy, JCEM, 86(2):504-510, 2001.	
C35	ROSSINI et al., Metabolic and endocrine studies in a case of lipoatrophic diabetes, Metabolism, 26(6):637-650, 1977.	
C36	SCHAMBELAN et al., Recombinant human growth hormone in patients with HIV-associated wasting: a randomized, placebo-controlled trial, Intern. Med., 125:873-882, 1996.	
C37	SEIP et al., Generalized lipodystrophy, congenital and acquired (lipoatrophy), Acta Paediatr. Suppl., 413:2-28, 1996.	
C38	SINGH et al., Modified forms of human growth hormone, Endocrinol., 94(3):883-891, 1974.	
C39	SKLAR et al., HIV infection and cardiovascular disease - is there really a link?, N. Engl. J. Med., 349(21):2065-2067, 2003.	
C40	STEIN, Protease inhibitors, coronary disease possibly linked, AIDS Weekly via NewsRx.com (22 November 1999).	П
C41	THORLACIUS-UZZING, Zinc in the anterior pituitary of rat: a histochemical and analytical work, Neuroendocrinol., 45:233-242, 1987.	

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Substitute for form 1449/PTO				Complete if Known		
Substitute for form 1775 175				Application Number	10/586,107-Conf. #1782	
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(Use as many sheets as necessary)			necessary)	Examiner Name	Not Yet Assigned	
Sheet	3	of	3	Attorney Docket Number	30694/39646B	

C42	TORRES et al., The effect of recombinant human growth hormone on protease-inhibitor- associated fat maldistribution syndrome [Abstract 675], 6th Conference on Retroviruses and Opportunistic Infections, 1999.	
C43	TORRES et al., Treatment of dorsocervical fat pads and truncal adiposity with serostim (recombinant human growth hormone) in patients with AIDS maintained on HAART, [Abstract 32164], 12th World AIDS Conference, Geneva, 1998.	
C44	VELDHUIS et al., Differential impact of age, sex steroid hormones, and obesity on basal versus pulsatile growth hormone secretion in men as assessed in an ultrasensitive chemiluminescence assay, JCEM, 80(11):3209-3222, 1995.	
C45	VELDHUIS et al., Dual defects in pulsatile growth hormone secretion and clearance subserve the hyposomatotropism of obesity in man, JCEM, 72(1):51-59, 1991.	П
C46	VIGOUROUX et al., Diabetes, insulin resistance and dyslipidaemia in lypodystrophic HIV- infected patients on highly active antiretroviral therapy (HAART), Diabetes Metab., 25:225- 232, 1999.	
C47	WANKE et al., Recombinant human growth hormone improves the fat redistribution syndrome (lipodystrophy) in patients with HIV, AIDS, 13:2099-2103, 1999.	
C48	WINDISCH et al., Recombinant human growth hormone for AIDS-associated wasting, Ann. Pharmacother., 32:437-445, 1998.	
C49	Written Opinion of the International Searching Authority, PCT/EP2005/000758, European Patent Office, 28 April 2005.	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner		Date	03/18/2008
Signature	/Gyan Chandra/	Considered	03/16/2006
Signature	,	Considered	

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.